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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,258	12/04/2003	James Boll	CYNO-16	7798

7590 12/01/2005
Donald N. Halgren
35 Central Street
Manchester, MA 01944

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,258	BOLL ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed 10/26/2005 have been fully considered but they are not persuasive.

The indicated allowability of claims 22 and 23 is withdrawn in view of the reevaluation of references to Loeb. Rejections based on the newly cited reference(s) follow.

Drawings

This application lacks formal drawings. The informal drawings filed in this application are marginally acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The cooling of the fluid of claim 3 is not cited in the specification. While temperature control is disclosed, cooling is not.

The disclosure is objected to because of the following informalities:

The text at the beginning of page 9 does not seem to logically follow that on page 8. The phrase "and repetition rates of (bottom of page 8) utilized since it is flexible (top of page 9)" is not understood.

The phrase "around 30 + or – thirty " on page 9 (also page 24) is not clear. If the intent is 30 ± 30 J, it would be more clearly stated as from 0-60 J. A similar statement appears on page 24, line 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 24 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent

Application Publication US 2003/0060813 to Loeb et al. Loeb et al. teach a device for applying radiant energy to tissue surrounding or underlying the surface of a duct, hollow organ or body cavity, particularly an esophagus (paragraph 0013). The energy is emitted through an expandable, energy-transmissive balloon in which a fluid coolant is circulated to cool the surface of the duct, hollow organ or body cavity and the tissue immediately underlying the surface of the duct, hollow organ or body cavity. The device includes an elongated transmission line extending through a catheter, having a proximal end portion, which is connectable to a source of radiant energy, and a distal end portion, to which a radiant energy emitter is coupled. The balloon is mounted on the distal end of the catheter and extends over the emitter. The catheter contains an inlet confined fluid passageway and an outlet confined fluid passageway to provide fluid coolant circulation through the balloon. A method aspect of this invention contemplates the positioning of an expandable coolant balloon carried by the distal end of an energy-emitting catheter adjacent a tissue to be treated. The catheter includes a radiant energy emitter at least partially surrounded by the balloon. Thereafter, one method aspect contemplates first circulating fluid coolant through the expandable coolant balloon to expand the coolant balloon

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and cool the tissue in contact with the coolant balloon, and then energizing the emitter at a predetermined power level to emit radiant energy so as to irradiate the tissue to produce a zone of shrinkage, coagulation or scar tissue in the irradiated tissue, while continuing to circulate fluid coolant through the balloon to preserve the integrity of the duct or endothelial lining of the hollow organ or body cavity (paragraph 0011). The radiant energy may be from a KTP laser (532 nanometers) using fibers with a diameter of from 500 to 1000 microns (paragraph 0090).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10, 12, 13, 17-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0060813 to Loeb et al. ('813) in view of U.S. Patent 6,635,052 to Loeb ('052). '813 is discussed above and further teaches microscopic albumen microspheres or particles of quartz or silica are suspended in the fluid coolant to more uniformly diffuse the radiant energy (abstract), deflating the balloon (paragraph

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0109), using a cooled saline solution for expanding the balloon (paragraph 0047) and use with an endoscope. The insertion of the balloon through a lumen in the endoscope inherently places the balloon at the distal end of the endoscope. '813 does not disclose pulse widths. '052 teaches a pulse repetition rate of 3-30 Hz (Col. 9, line 12). Such a rate yields a pulse width of about 16 ms at the 30 Hz rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the treatment pulse widths as taught by '052 in the method of '813 as both devices and methods are for treating the tissue lining an esophagus.

Claims 8, 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0060813 to Loeb et al. ('813) in view of U.S. Patent 6,635,052 to Loeb ('052) as applied to claim 1 above and further in view of U.S. Patent 5,409,483 to Campbell et al. '052 and '813 are discussed above, but do not disclose a visualization capability or positionable fiber. Campbell et al. teach a surgical probe for use in a hollow vessel or other region of the body which comprises a multi-lumen catheter having a transparent, non-compliant balloon coupled to the distal end, such that the balloon has a known shape when inflated. A direct visualization scope is provided in a first lumen of the multi-lumen catheter providing direct visualization into the hollow vessel through the non-compliant balloon (abstract). An inflation lumen and a deflation lumen are disclosed implying a means for inflation and deflation of the balloon (Col. 7, lines 60-61). A fiber optic is provided in a third lumen of the multi-lumen catheter to deliver light energy to the hollow vessel through the non-compliant balloon, which may be configured with a cylindrical section or other desired shape. Within the balloon, a mechanism is provided for positioning the light emitting tip of the fiber optic within the balloon (Col. 3, lines 47-54). The fiber may emit the light from a side (Fig. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the visualization and fiber positioning as taught by Campbell et al. in the method of '813 and

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'052 as '813 clearly teaches use with an endoscope and the primary function of an endoscope is for visualizing for positioning for a treatment.

Claims 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0060813 to Loeb et al. ('813) in view of U.S. Patent 6,635,052 to Loeb ('052) as applied to claims 1 and 13 above and further in view of U.S. Patent 6,755,849 to Gowda et al. '052 and '813 are discussed above, but do not disclose the use of a plurality of fibers or an endoscope within a treatment balloon. Gowda et al. disclose a method for delivering energy to a tissue. The method includes providing an apparatus which includes an energy delivery component and an inflatable member disposed around the energy delivery component (abstract). The method may be used to treat Barrett's esophagus (Col. 1, line 33). The thermal delivery apparatus is inserted into an esophagus under local anesthesia and positioned under endoscopic (use with an endoscope) guidance at the level of lower esophageal sphincter. Once at the desired position, inflatable member is inflated such that inflatable member engages the walls of esophagus (purging). Optical energy (e.g., laser light) is then delivered through optical delivery component (Fig. 3A, # 46, note it is within the balloon). Multiple optical fibers may be used for delivery of the laser energy (Col. 7, lines 16-20). The invention can be practiced using a thermal delivery apparatus configured such that optical energy is delivered to only a portion of the LES. Optical delivery component can then be made to mechanically (articulate) scan the tissue to create a homogenous lesion along any desired length of the LES. Such mechanical scanning can be carried out, for example, by moving optical delivery component axially relative to central lumen of the tubular housing or by deflating inflatable member, moving thermal delivery apparatus relative to LES, and repeating the procedure (Col. 10, lines 4-31). The cooling fluid may be saline (Col. 11, line 31). The endoscope (Fig. 2A, # 42) is within the balloon (Fig. 2A, # 44). It is inherent the balloon is

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optically transparent as the energy delivery component passes through the inflatable member's inner wall, through the cooling fluid disposed in the cavity, through the inflatable member's outer wall, and into the tissue (Col. 9, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the multiple fibers and endoscope within the balloon as taught by Gowda et al. in the method of '052 and '813 as the use of multiple fibers for redundancy is common and the placement of the visualization is an elementary art skill based on the visualization needs of the treatment.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0060813 to Loeb et al. ('813) in view of U.S. Patent 6,635,052 to Loeb ('052) as applied to claim 1 above and further in view of U.S. Patent Application Publication US 2004/0249243 to Kleiner. '052 and '813 are previously discussed, but do not disclose a window at the distal end of the balloon. Kleiner teaches a device for use in a body cavity with an expandable balloon that includes a window portion on the distal end (paragraph 0086) for visualization. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the window as taught by Kleiner in the device of '052 and '813 to provide visual guidance for the proper positioning of the device as such visualization is pervasive and providing a window in a specific position for a procedure is well within the skill of the art.

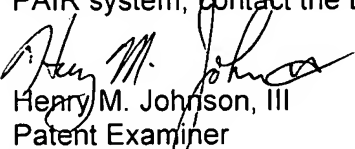
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Patent Examiner
Art Unit 3739

